

Butler, Jennie C

From: default [default@nih.gov]
Sent: Thursday, June 13, 2002 1:43 PM
To: FDADockets@oc.fda.gov; vfalanga@bu.edu
Subject: Docket No. 02N-0169 "Combination Products Containing Live Cellular Components"

Dear Sirs/Madams:

I am writing about Docket No. 02N-0169 "Combination Products Containing Live Cellular Components Hearing". I request to be a participant in this hearing:

Name: Vincent Falanga, MD, FACP
Address: Dept. of Dermatology, Roger Williams Medical Center, 50 Maude Street, Providence, RI 02908. Tel. 401-456-2521; Fax. 401-456-6449;
E-mail: vfalanga@bu.edu
Institution: Boston University, Professor of Dermatology and Biochemistry
Sponsor: None

Time Requested: 15 minutes

Summary: We have had considerable experience with these products, both from the clinical standpoint as well as investigating their mode of action in the laboratory. We have found them to be highly effective for the treatment of chronic wounds but remain uncertain about their mechanisms of action. Several things worth noting and which are relevant to this meeting: 1) Constructs do not seem to remain in the wound after several weeks; 2) Constructs create an environment conducive to healing and, in that sense, can be thought of as advanced and active dressings. Their action stimulates the wound to heal; 3) Although most of these living constructs produce cytokines and growth factors, it is by no means certain that this represents their mode of action. In fact, at least in vitro, they may not be active in stimulating other cells to proliferate. Most likely, the construct modify the environment of the wound and provide a scaffold for host cells. It is our view they these constructs should be treated as devices until we know more about their mode of action.

Thank you,

Vincent Falanga, MD, FACP

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